PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 80081 MBE/TR	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2004/013963	International filing date *(day/month/year)* 08.12.2004	Priority date *(day/month/year)* 08.12.2003
International Patent Classification (IPC) or national classification and IPC A61K7/16, A23G3/00		
Applicant CADBURY SCHWEPPES PLC et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07.10.2005	13.03.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Paloniemi Legland, R Telephone No. +49 89 2399-7315

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/013963

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-14	as originally filed
Claims, Numbers	
1-21	received on 07.10.2005 with letter of 06.10.2005
Drawings, Sheets	
1/1	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☒ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☒ the claims, Nos. 22-23
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-21
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-21
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-21
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO 03/002056 A (CHURCH & DWIGHT CO., INC) 9 January 2003 (2003-01-09)
D2: US 2003/072841 A1 (RAJAIAH JAYANTH ET AL) 17 April 2003 (2003-04-17)
D3: WO 03/017964 A (UNILEVER N.V; UNILEVER PLC; HINDUSTAN LEVER LTD) 6 March 2003 (2003-03-06)
D4: WO 99/12517 A (SMITHKLINE BEECHAM CORPORATION; SMITHKLINE BEECHAM PLC; CASH, MICHAEL;) 18 March 1999 (1999-03-18)
D5: US 2003/072722 A1 (NATHOO SALIM A) 17 April 2003 (2003-04-17)
D6: DE 36 45 147 C2 (COLGATE-PALMOLIVE CO., NEW YORK) 9 November 2000 (2000-11-09)
D7: GB-A-1 018 665 (UNILEVER LIMITED) 26 January 1966 (1966-01-26)

The document D4 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses tooth whitening preparations comprising water soluble alkali metal tripolyphosphate in combination with an alkali metal pyrophosphate salt.
The subject-matter of claim 1 differs from this known teeth whitening composition in that the composition of claim 1 is in a form of **lozenge** and that the whitening agent comprises **calcium pyrophosphate.**

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as to provide an alternative tooth whitening composition having an improved whitening effect.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The solution proposed in claim 1 may be regarded as being an inventive selection. Document D4 discloses calcium pyrophospahte as one of the suitable abrasives (p.9,

I.1-3). Furthermore, the whitening compositons of D4 may be presented in any of the conventional formulations such as e.g. lozenge (p.8, l.11-14).

Document D1 discloses a solid oral composition (e.g. lozenge) to inhibit formation of plaque comprising calcium pyrophosphate, sodium bicarbonate, sweeteners and antibacterial agents.

Document D2 discloses chewing gum and confection compositions for plaque inhibition comprising e.g. calcium pyrophosphate, alkali metal bicarbonate salts, vitamin C, urea, whitening agents, flavouring agents and antibacterial agents.

Document D3 discloses oral compositions to clean the oral cavity (e.g. lozenge, gum) comprising calcium pyrophosphates, bicarbonate, vitamin C, urea, anti-calculus agents and flavours.

Document D5 discloses tooth whitening hydrogels comprising sodium pyrophosphate.

Document D6 discloses oral compositions (lozenge) for removing the stain comprising alkaline pyrophosphates and bicarbonate.

Document D7 discloses dentifrices comprising calcium pyrophosphate, sodium methaphosphate, flavours and anti-bacterial agents.

None of the prior art documents D1-D7 discloses a lozenge composition comprising calcium pyrophosphate.

Although calcium pyrophosphate is proposed as an abrasive agent in oral formulations in the prior art documents, no hints can be found in the prior art as to any unexpected effect of calcium pyrophosphate as a whitening agent (more effective than the other abrasive agents) when formulated as a lozenge.
Thus, the subject-matter of claim 1 involves an inventive step.

Claims 16-18 are directed to a use of a lozenze composition of claim 1 for tooth whitening and claims 19-21 to a method of whitening tooth surfaces by consuming the lozenge of claim 1. The same reasoning as to claim 1 applies also to these claims.
Claims 2-15 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.

PCT/EP2004/013963

Claims

1. A solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials, said composition comprising:

a) a lozenge base,

b) conventional lozenge additives,

c) a tooth whitening agent comprising calcium pyrophosphate.

2. A composition according to claim 1 in which said calcium pyrophosphate is present in an amount of between 0.1 and 10% by weight of the composition.

3. The composition according to claim 2 in which said calcium pyrophosphate is present in an amount of between 0.5% and 9%, preferably between 1.0 % and 6.5 %, even more preferably between 1.5 % and 4.0 %, by weight of the composition.

4. The composition according to any of the preceding claims in which said conventional lozenge ingredients comprise one or more of the following: sweeteners, high intensity sweeteners, taste enhancers, flavouring agents, colouring agents.

5. The composition according to any of the preceding claims in which said composition is essentially sugar-free.

6. The composition according to any of the preceding claims comprising one or more additional tooth whitening agents.

7. The composition according to claim 6 in which said additional tooth whitening agent(s) is/are present in between 0.01% and 5.0%, more particularly between 0.05 and 1.0%, most preferably between 0.1% and 0.5% by weight of the composition.

8. The composition according to claim 6 or 7 in which said additional tooth whitening agent comprises a bicarbonate salt.

9. The composition according to claim 8 in which said additional tooth whitening agent comprises sodium bicarbonate, said agent being present in between 0.1% and 0.5% by weight of the composition.

10. The composition according to any of the preceding claims in which said additives and/or tooth whitening agents are encapsulated.

11. The composition according to any of the preceding claims further comprising one or more of the following: oral hygiene promoting agents, anti-calculus agents, anti-microbial agents, anti-inflammatory agents, desensitising agents, therapeutically active agents, remineralising agents.

12. The composition according to any of the preceding claims further comprising a supplement.

13. The composition according to claim 12 in which said supplement comprises vitamin C.

14. The composition according to claim 11 in which the oral hygiene promoting agent comprises urea, said urea being present in between 0.1% and 25%, particularly between 0.4% and 10%, preferably between 0.6% and 5.0%, more preferably between 0.7 % and 3.5%, even more preferably between 0.8 % and 2.5% by weight.

15. The composition according to any of the preceding claims in the form of hard-boiled lozenges.

16. A use of a composition according to any of the preceding claims to whiten tooth surfaces.

17. A use of a composition according to claims 1-15 to whiten tooth surfaces, said

tooth surfaces being discoloured after use of red wine or related products.

18. A use of a composition according to any of the claims 1-15 to whiten tooth surfaces, said tooth surfaces being discoloured after use of coffee-related products.

19. A method of whitening tooth surfaces by consuming a solid, oral tooth whitening lozenge composition according to any of claims 1-15.

20. A method of whitening tooth surfaces by consuming a solid oral tooth whitening lozenge composition according to claims 1-15, said tooth surfaces being discoloured after use of red wine or related products.

21. A method of whitening tooth surfaces by consuming a solid oral tooth whitening lozenge composition according to any of the claims 1-15, said tooth surfaces being discoloured after use of coffee-related products.